

## **REMARKS**

Submitted concurrently herewith is an Information Disclosure Statement with several prior art references, including Japanese Patent Application Laid-open No. Hei 6-241986. Certain portions (paragraph 023 and the claims) of Hei 6-241986 were cited by the Japanese Patent Office in the corresponding Japanese application. A translation of the Japanese patent office communication and those portions of Hei 6-241986 cited therein are also provided in the IDS. Applicant respectfully requests that the Examiner consider the contents of the IDS and include an indication that the same have been considered in the next communication.

Claims 1-9 have been canceled. New Claims 10-21 have been added.

New Claims 10-21 are directed toward an embodiment of the invention in which a plurality of optical density waveforms (e.g., a first optical density waveform corresponding to cholesterol and a second optical density waveform corresponding to triglyceride) representing different components of a plurality of lipoproteins (e.g., HDL, LDL, VDL and chylomicron) are normalized. The portions of the normalized optical density waveforms corresponding to the different components are then added together to form totals of the components for each of the different proteins. Thus, for example, the portion of the normalized cholesterol optical density waveform corresponding to HDL is added to the portion of the normalized triglyceride optical density waveform corresponding to HDL to form a total HDL value. The total values for the different lipoproteins are then compared to corresponding reference values, and a phenotype is determined based on the comparison.

The prior art of record neither discloses nor suggests the inventions of Claims 10-21. Kaneko discloses comparing a normalized electrophoretic image of a test specimen with an electrophoretic images of standard specimen. Kaneko does not disclose using waveforms for different components of the same lipoproteins. In this regard, applicants note that the office

action erroneously stated that Kaneko discloses “different examination items for a single analyte” at col. 4, lines 14-17 and 21-30. Applicants respectfully disagree. As used in the specification, an “examination item” corresponds to a component of a lipoprotein such as cholesterol or lipoprotein (see, e.g., Figure 8, showing the selection of cholesterol under the heading “examination item”) (applicants have used the term “protein components” rather than “examination items” in new claims 10-21 to avoid confusion on this point). In contrast, the cited passages of Kaneko refer to entire proteins of a serum sample of a human being rather than components of proteins. Kaneko neither teaches nor suggests the desirability of examining the different components of the proteins of a serum sample.

The office action also relied on the teaching in the “Background” portion of the specification that a core part of lipoprotein includes triglyceride and cholesterol ester, and that electrophoretic lipoprotein separation is employed in routine examination. Office Action, page 2. However, knowledge that lipoprotein cores include cholesterol and triglycerides and that electrophoretic separation of lipids into various proteins is often done during phenotypic classification of hyperlipemia, even when combined with Kaneko, does not make the inventions of Claims 10-21 obvious because there is no teaching or suggestion in any of the foregoing of using multiple waveforms for calculating totals of different components for a plurality of proteins and comparing these totals to reference values to determine a phenotype. By providing these features, the invention of Claims 10-21 can provide a stable, reliable phenotype determination automatically without reliance on human judgement as is done in the prior art.

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact Applicants counsel, James M. Heintz at (202) 861-4167.

Respectfully submitted,

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